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5. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K090057.

Submitter's Identification:

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Date Prepared: January 7, 2009

Contact Person:

Richard Lenart
Regulatory Affairs Manager

Proprietary Name of the Device:

On-Call® Plus Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System
(To be manufactured and marketed for consumer home and professional use)

Predicate Device:

One Touch Ultra Blood Glucose Monitoring System
Lifescan, Inc., located at 1000 Gibraltar Dr., Milpitas, CA 95035, USA.
510(k) Number: K002134

Device Name: On-Call® Plus Blood Glucose Monitoring System

Proprietary Name	Classification	ProCode	Description	Common Name
On-Call® Plus Blood Glucose Monitoring System	862.1345 Class II	75 NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
On-Call® Plus Blood Glucose Meter and On-Call® Plus Blood Glucose Test Strips	862.1345 Class II	75 CGA	Glucose Monitor	Glucose Meter & Test Strips
On-Call® Plus Glucose Control Solution	862.1660 Class I	75 JJX	Single Analyte Control	Control Solution
On-Call® Plus Lancets and On-Call® Plus Lancing Device	878.4800 Class I	79 FMK	Lancet, Blood	Lancets

Description:

The On-Call® Plus Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip, palm, and/or forearm. The glucose measurement is achieved by using the amperometric detection method.

The test strip has a reagent system including glucose oxidase and a mediator that reacts with glucose in the whole blood sample to produce an electrical current. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading is displayed on the meter display, calibrated to a plasma reference.

Intended Use:

The On-Call® Plus Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in capillary whole blood from the fingertip, forearm, and/or palm by people with diabetes at home and by healthcare professionals as an aid in the monitoring the effectiveness of diabetes control programs.

Technological Characteristics:

Specification of Blood Glucose Meter:

Feature	Specification
Measurement Range	1.1-33.3 mmol/L (20 to 600 mg/dL)
Result Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Minimum Sample Size	1 µL
Test Time	10 seconds
Power Source	One (1) CR 2032 3.0V coin cell battery
Battery Life	12 months or approximately 1,000 tests
Glucose Units of Measure	The meter is pre-set at time of manufacturing to either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the country of use standard
Memory	Up to 300 records with time and date
Meter Size	85 mm x 54 mm x 20.5 mm
Display Size	35 mm x 32.5 mm
Weight	Approximately 49.5 g (with battery installed)
Operating Temperature	5-45°C (41 - 113°F)
Operating Relative Humidity	20-90% (non-condensing)
Hematocrit Range	30-55%
Data Port	9600 baud, 8 data bits, 1 stop bit, no parity
Sample Site	Fingertip, palm and forearm

Comparison to Predicate Devices:

The On-Call® Plus Blood Glucose Monitoring System is substantially equivalent to the One Touch Ultra Blood Glucose Monitoring System, K002134.

Features	On-Call® Plus Blood Glucose Monitoring System	One Touch Ultra Blood Glucose Monitoring System (K002134)
Similarities		
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)	Same
Result Calibration	Plasma-equivalent	Same
Sample	Fresh capillary whole blood	Same
Minimum Sample Size	1 µL	Same
Assay Method	Glucose oxidase biosensor	Same
Power Source	One (1) CR 2032 3.0V coin cell battery	Same
Battery Life	12 months or approximately 1,000 tests	Same
Glucose Units of Measure	mg/dL	Same
Hematocrit Range	30-55%	Same
Automatic Shutoff	Two minutes after last user action	Same
Data Port	One data port	Same
Differences		
Test Time	10 seconds	5 seconds
Memory	Up to 300 records with time and date	150 blood glucose and control solution tests
Meter Size	85 mm x 54 mm x 20.5 mm	3.12" x 2.25" x 0.85"
Weight	Approximately 49.5 g (with battery installed)	1.5 ounces with battery (Approximately 42 g)
Operating Temperature	5-45°C (41 - 113°F)	6-44°C (43 - 111°F)
Operating Relative Humidity	20-90% (non-condensing)	10-90%
Sample Site	Fingertip, palm and forearm	Fingertip and forearm

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents included the "FDA Guidance for Industry In Vitro Diagnostic Glucose Test System" and "FDA Guidance for Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems" as well as "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Compliance to applicable voluntary standards includes EN ISO 15197:2003 "In vitro diagnostic test systems – Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus".

Laboratory Testing:

The performance characteristics of the On-Call® Plus Blood Glucose Monitoring System were evaluated by performing the following studies: repeatability precision, intermediate precision, linearity, interfering agents, hematocrit effect, temperature effect evaluation – blood & control solution, low battery effect, altitude effect, sample volume, software validation testing, electromagnetic compatibility and electrical safety testing as part of meter and strip validation testing.

Discussion of Clinical Tests Performed:

Clinical studies were conducted with lay persons and trained laboratory technicians using the On-Call® Plus Blood Glucose Monitoring System. The study data were presented evaluating the system accuracy of the On-Call® Plus Blood Glucose Monitoring System compared to the YSI Model 2300 STAT PLUS (K913806) per the ACON Clinical Study Protocol for the Blood Glucose Monitoring System. Study results indicate that non-professional, inexperienced lay persons were able to obtain comparable blood glucose readings when using the On-Call® Plus Blood Glucose Monitoring System as compared to the results obtained by the trained technicians. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the On-Call® Plus Blood Glucose Monitoring System.

Conclusion:

The laboratory testing and clinical study results demonstrate that the On-Call® Plus Blood Glucose Monitoring System is safe, effective and easy-to-use. It also demonstrates that the On-Call® Plus Blood Glucose Monitoring System meets the accuracy requirements per ISO 15197 and as such is substantially equivalent to the One Touch Ultra Blood Glucose Monitoring System, currently sold on the U.S. market (K002134).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Acon Laboratories Co.
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4108 Sorrento Valley Blvd.
San Diego, CA 92121

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Re: k090057
Trade/Device Name: On-Call Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: January 07, 2009
Received: January 08, 2009

Dear Mr. Lenart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k090057

Device Name: On-Call® Plus Blood Glucose Monitoring System

Indication For Use:

The On-Call® Plus Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in capillary whole blood from the fingertip, forearm, and/or palm by people with diabetes at home and by healthcare professionals as an aid in the monitoring the effectiveness of diabetes control programs.

The On-Call® Plus Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.

The On-Call® Plus Blood Glucose control solution is for use with the On-Call® Plus Blood Glucose meter and strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use _____ And/Or Over the Counter Use _X_.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k090057